LIDOZEN- lidocaine, menthol patch
Beijing HKKY Medical Tech. Co., Ltd.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Lidozen Patch

DRUG FACTS:

ACTIVE INGREDIENTS:

Lidocaine 4.00%

Menthol 1.00%

Topical Anesthetic

External Analgesic

USES:

For temporary relief of pain

WARNINGS:

- For external use only.
- Avoid contact with eyes.
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a physician.

Do not use

- in large quantities, particularly over raw surfaces or blistered areas.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

- If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS (Adults and Children Over 12 Years):

Clean and dry affected area.

Remove patch from backing and apply to affected area.

Use only one patch at a time, and maximum of four patches / day.

Leave patch on affected area for up to 8 hours

Do not use patches for longer than five consecutive days,

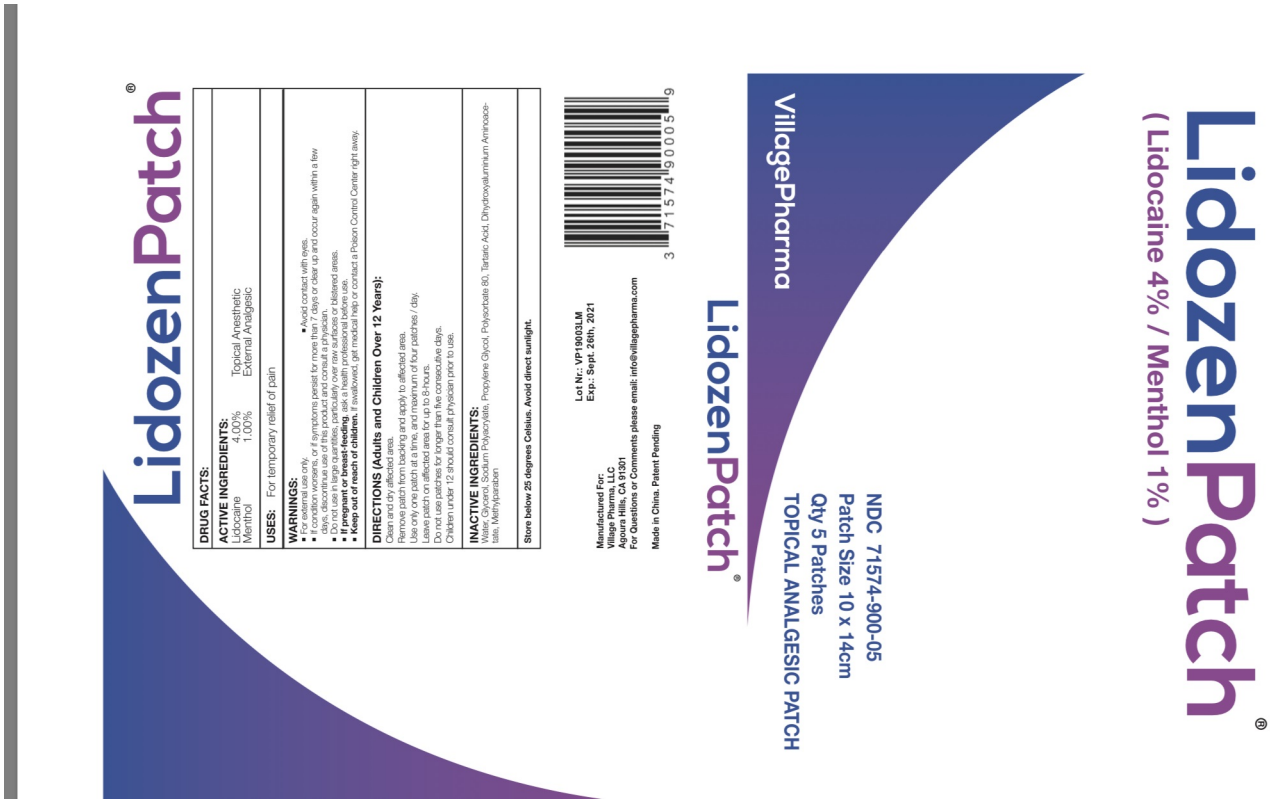
Children under 12 should consult physician prior to use.

INACTIVE INGREDIENTS:

Water, Glycerol, Sodium Polyacrylate, Propylene Glycol, Polysorbate 80, Tartaric Acid, Dihydroxyaluminium Aminoacetate, Methylparaben

Store below 25 degrees Celsius, Avoid directe sunlight.

Package Labeling:



LIDOZEN

lidocaine, menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71073-203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TARTARIC ACID (UNII: W4888I119H)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71073-203-01	5 in 1 POUCH	11/20/2019	
1		1 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/20/2019	

Labeler - Beijing HKKY Medical Tech. Co., Ltd. (544434817)

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